

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

KEVIN MATTHEW ABLES (DECEASED),
by and through his mother and next of kin,
JUDY N. ABLES, *et al.*

Plaintiffs,

v.

AMERISOURCEBERGEN DRUG
CORPORATION; CARDINAL HEALTH,
INC.; MCKESSON CORPORATION;
PURDUE PHARMA L.P.; PURDUE
PHARMA, INC.; THE PURDUE FREDERICK
COMPANY, INC.; TEVA
PHARMACEUTICAL INDUSTRIES,
LTD.; TEVA PHARMACEUTICALS USA,
INC.; CEPHALON, INC.; JOHNSON &
JOHNSON; JANSSEN PHARMACEUTICALS,
INC.; ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. f/k/a JANSSEN
PHARMACEUTICA, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; NORAMCO,
INC.; ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC. n/k/a
ACTAVIS, INC.; WATSON LABORATORIES,
INC.; ACTAVIS LLC; ACTAVIS PHARMA,
INC. f/k/a WATSON PHARMA, INC.;
MALLINCKRODT PLC; MALLINCKRODT
LLC;

Defendants.

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

CIVIL ACTION NO. _____

COMPLAINT
JURY TRIAL DEMANDED

Plaintiffs, Kevin Matthew Ables (deceased), by and through his mother and next of kin, Judy N. Ables, *et al.*, brings this lawsuit against Defendants Purdue Pharma L.P., Purdue Pharma, Inc., The Purdue Frederic Company Inc., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Jansen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceuticals Inc. n/k/a Janssen Pharmaceuticals, Inc. Endo Health Solutions Inc., Endo Pharmaceuticals, Inc. Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Mallinckrodt, PLC., McKesson Corporation, AmerisourceBergen, and Cardinal Health, Inc. (collectively, the “Defendants”). In order to remedy the harm to Plaintiffs from Defendants’ wrongful conduct and the unjust profits and other benefits repeated by the Drug Companies and Distributors, Plaintiffs bring this action on behalf of themselves, as defined below.

INTRODUCTION

1. Drug companies should never place their desire for profits above the health and well-being of their customers or the communities where those customers live. Because they know prescribing doctors and other health-care providers rely on drug companies’ statements in making treatment decisions, drug companies must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence.

2. Defendants broke these simple rules and helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in the United States, including Mississippi.

3. Defendants manufacture, distribute, market, and sell prescription opioids (“Opioids”), including brand name drugs like Oxycontin and Percocet, and generics like

oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain, migraines, and arthritis),¹ opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

4. By the late 1990s, however, and continuing today, each Defendant began a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain. As to the risks, Defendants falsely and misleadingly, and contrary to the language on their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support Defendants' claims.

5. Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians Defendants recruited for their

¹ In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

support of Defendants' marketing messages. Borrowing a page from Big Tobacco's playbook, Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs"); and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (appropriately labeled "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients have traditionally relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

6. Each Defendant knew that its misrepresentation of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration (the "FDA") and the Centers for Disease Control and Prevention (the "CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain* (See Exhibit 1 to this Complaint), issued in 2016 and approved by the FDA (the "2016 CDC Guideline"). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlement agreements with public entities that prohibit them from making many of the representations identified in this Complaint in other jurisdictions. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term opioid use in

the United States, including Mississippi, and continues to fail to correct its past misrepresentations.

7. Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drug; they generated \$11 billion in revenue for drug companies in 2104 alone. In an open letter to the nation's physicians in August 2016, the United States Surgeon General at the time expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."² This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the streets to buy prescription opioids or even heroin.

8. It is hardly necessary to say that every State in the United States is now awash in opioids and engulfed in a public health crisis the likes of which have not been seen before. From 2014 to 2016, Mississippi has consistently been ranked within the top 5 states nationally when it comes to rates of opioid prescriptions dispensed per 100 persons by dosage and type at 116.3, 111.0 and 105.6 respectively.³

9. In 2016 and 2017, despite this consistent decline, Mississippi had the fourth highest opioid prescription rate in the nation, exceeded only by Tennessee, Arkansas, and Alabama.⁴

² Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at <http://turnthetidex.org/>.

³ Centers for Disease Control and Prevention, *Annual Surveillance Report Of Drug-Related Risks And Outcomes*, U.S., 2017. <https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf>.

⁴ Mississippi State Department of Health, *Mississippi Morbidity Report*, Vol. 34, No. 1; November 2018. https://msdh.ms.gov/msdhsite/_static/resources/7863.pdf. (See Centers for Disease Control and Prevention. 2018 Annual Surveillance Report of Drug-Related Risks and Outcomes – United States. Surveillance Special Report.

10. The results of Mississippi's opioid crisis have been catastrophic. Opioids have become the main source of unintentional drug overdose in the state, due to the vast supply of opioids; the number of annual deaths attributable to unintentional drug overdoses has rapidly increased in recent years.⁵ Most of the deaths (643 or 89.9%) were unintentional; however, 34 cases (4.8%) were due to suicide.⁶ Among the 715 opioid overdose deaths, 11.7% (84 cases) involved at least one more opioid and 43.6% (312 cases) involved at least one more non-opioid drug of abuse.⁷ Additionally, from 2011 to 2016, Mississippi observed a 126.3% increase in opioid related deaths.⁸

11. But even these alarming statistics do not fully illustrate the toll of prescription opioid abuse on patients and their families, as the dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek drugs from doctors. Efforts by physicians to reverse course for a chronic pain patient with long-term dependence on opioids are often thwarted by a secondary criminal market well stocked by a pipeline of drugs that are diverted to supply these patients.

12. Prescription opioid abuse has not displaced heroin, but rather triggered resurgence in its use, imposing additional burdens on state agencies and others that address heroin use and addiction. This is evident, as Mississippi has seen a tremendous increase in treatment admissions for opioid use disorders involving heroin. From 2015 to 2017 the number of admissions and

Centers for Disease Control and Prevention. U.S. Department of Health and Human Services. Published August 31, 2018.)

⁵ The Mississippi State Department of Health reports that the number of Mississippi deaths from opioid-related drug overdose between 2011 and 2016 – was 715. Mississippi State Department of Health, *Drug Overdose Deaths Involving Opioids In Mississippi, 2011-2016*. The Mississippi Opioid Project, Epidemiological Report, 2/2/2018. https://msdh.ms.gov/msdhsite/_static/resources/7550.pdf.

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

unique patients for treatment due to heroin increased 114% and 121% respectively.⁹ Individuals who are addicted to prescription opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high.¹⁰

13. Many thousands of U.S. citizens suffer from chronic pain, which takes an enormous toll on their health, lives, and families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about risks and benefits. But Defendants' deceptive marketing campaign deprived Mississippi patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

14. The opioid epidemic is a contemporary and continuous public nuisance and remains unabated.

15. Defendants' misrepresentations and deceptive conduct has exacted, and foreseeably so, a heavy financial burden on this United States, including Mississippi. To redress and punish these violations of the states' statutory and common law, including the Mississippi Unfair and Deceptive Trade Practices Act, Plaintiffs, on their own behalf seek damages for the actual damage and injury they have suffered by paying for excessive opioid prescriptions and in connection with the results of those prescriptions (for example, and not limited to, addiction treatment costs). Plaintiffs also seek attorneys' fees and costs pursuant to Miss. Code Ann. § 11-

⁹ Mississippi Opioid And Heroin Data Collaborative, *Provisional Data Report Third Quarter of 2018*, November 28, 2018. https://msdh.ms.gov/msdhsite/_static/resources/8049.pdf.

¹⁰ See, e.g., Kate Jordan, *Police: Heroin becoming more Prevalent in Fort Smith Region*, *Southwest Times Record*, Oct. 2, 2016, www.swtimes.com/news/20161002/police-heroin-becoming-more-prevalent-in-fort-smith-region ("One of the reasons heroin is making a comeback is because people are so addicted to pharmaceuticals – opiates and opioids, and heroin is cheaper." (Quotation omitted)).

55-7, *et seq.* Plaintiffs also seeks costs of future medical monitoring made necessary by Defendants' unlawful actions.

JURISDICTION AND VENUE

16. This voluntarily discloses the data necessary to identify with specificity the transactions, which will form the evidentiary basis for the claims, associated herein.

17. This Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) because the Plaintiffs and Defendants are “citizens” of different states, and the amount in controversy as to their non-class claims exceeds \$75,000, exclusive of interest and costs.

18. This Court has personal jurisdiction over each Defendants because they conduct business within the continental United States of America, purposefully direct or directed their actions toward the states, some or all consented to be sued in Mississippi by registering an agent for service of process, they consensually submitted to the jurisdiction of Mississippi when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the states necessary to constitutionally permit the Court to exercise jurisdiction.

19. This Court has personal jurisdiction over all of the Defendants under 18 U.S.C. 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the “ends of justice” require national service of Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial.¹¹

20. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in

¹¹ See, e.g., *Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F.Supp. 2d 796(1998)(citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, *3(N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest. Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District 28 U.S.C. § 1391(b); 18 U.S.C. § 1965(a).

PARTIES

A. PLAINTIFFS

21. Plaintiffs are residents of the United States of America, who were prescribed opioids and who, over the following years, received prescriptions for various opioids. Some Plaintiffs were subsequently treated for addiction related to their opioid prescriptions or sought self-care treatment. (See Exhibit 2 for a list of Plaintiffs)

B. DEFENDANTS

1. Opioid Manufacturers

22. The Defendants within this subsection will be referred to throughout as the “Opioid Manufacturers.”

Purdue Defendants

23. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and the PURDUE FREDERICK COMPANY, INC. is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, “PURDUE”).

24. Purdue manufactures, promotes, sells, and distributes opioids such as Oxycontin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States. Oxycontin is Purdue’s best-selling opioid. Since 2009, Purdue’s annual sales of Oxycontin have fluctuated between \$2.47 billion and \$2.99 billion, up almost four-fold from its 2006 sales of \$800 million. Oxycontin constitutes roughly 30% of the entire market for analgesic drugs

(popularly known as painkillers).

Cephalon Defendants

25. CEPHALON, INC. (“CEPHALON”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICALS USA, INC. (“TEVA USA”) is a wholly-owned subsidiary of TEVA PHARMACEUTICAL INDUSTRIES, LTD. (“TEVA Ltd.”) and is a Delaware corporation with its principal place of business in New Wales, Pennsylvania. TEVA USA acquired Cephalon in October 2011.

26. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.”¹² Fentora have been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”¹³ In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug, and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.¹⁴

27. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display TEVA Ltd.’s logo.¹⁵ TEVA Ltd.’s financial reports list Cephalon’s and TEVA USA’s sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon

¹² Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s03011b.pdf.

¹³ Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s01511b.pdf.

¹⁴ Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

¹⁵ E.g., ACTIQ, [http://www.actiq.com/\(displaying logo at bottom left\)](http://www.actiq.com/(displaying+logo+at+bottom+left)).

acquisition – attributed to a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including *inter alia* sales of Fentora®.¹⁶ Through interrelated operations like these, TEVA Ltd. operates in the United States through its subsidiaries Cephalon and TEVA USA. The United States is the largest of TEVA Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of TEVA USA and Cephalon, TEVA Ltd. would conduct those companies’ business in the United States itself. TEVA Ltd. directs the business practices of Cephalon and TEVA USA, and their profits inure to the benefit of TEVA Ltd. as controlling shareholder.

28. TEVA Ltd., TEVA USA, and Cephalon work together closely to market and sell Cephalon products in the United States. TEVA Ltd. conducts all sales and marketing activities for Cephalon in the United States through TEVA USA and has done so since its October 2011 acquisition of Cephalon. TEVA Ltd. and TEVA USA hold out Actiq and Fentora as TEVA products to the public. TEVA USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in the United States, discloses that the guide was submitted by TEVA USA, and directs physicians to contact TEVA USA to report adverse events. The United States is the largest of TEVA Ltd.’s global markets, representing 53% of its global revenue in 2015. (Throughout the remainder of this Complaint, references to “Cephalon” encompass Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc.).

29. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, TEVA Ltd.

¹⁶ TEVA Ltd., Annual Report (Form 20-F) 62(Feb. 12, 2013).
http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

acquired Cephalon.

Janssen Defendants

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of JOHNSON & JOHNSON (“J&J”), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

31. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals’ drugs and Janssen’s profits inure to J&J’s benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as “Janssen”).

32. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid drug Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

33. NORAMCO, INC. (“Noramco”) is a Delaware company headquarters in Wilmington, Delaware. Noramco was a wholly owned subsidiary of J&J until July 2016.

Endo Defendants

34. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of ENDO HEALTH SOLUTIONS INC. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as “Endo”).

35. Endo develops, Markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydane, in the United States. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.5 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

Actavis Defendants

36. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Allegan plc is the product of a few acquisitions and mergers. In March 2015, Allergan plc was acquired by ACTAVIS PLC, and the combined company took the name “Allergan plc.” Actavis plc was itself the product of an acquisition: in October 2012, Watson Pharmaceuticals, Inc. acquired Actavis, Inc., and the combined company adopted the name “Actavis plc.”

37. WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company adopted the name of Actavis, Inc. as of January 2013 before finally settling on Actavis PLC in October 2013. WATSON LABORATORIES, INC. is a

Nevada Corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc.).

38. ACTAVIS PHARMA, INC. is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

39. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as “Actavis”).

40. Actavis manufactures, promotes, sells, and distributed opioids, including branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

Mallinckrodt Defendants

41. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

42. MALLINCKRODT, LLC is a limited liability company organized and existing under the law of the State of Delaware. Since 2013, Mallinckrodt, LLC has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to 2013, Mallinckrodt, LLC was a wholly-owned subsidiary of the Irish public limited company Covidien pllc (formerly known as Tyco Healthcare).

43. Mallinckrodt, plc and Mallinckrodt, LLC will be referred to collectively as

“Mallinckrodt.”

44. Mallinckrodt manufactures, markets, and sells drugs in the United States, including generic oxycodone, of which it is one of the largest manufacturers, and opioids sold since at least June 2009 under the brand names Exalgo (hydromorphone), Xartmis (oxycodone/acetaminophen) and Roxicodone (oxycodone)(known by the street names “M,” “roxies/roxys,” or “blues”). In July 2017 Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

2. Opioid Distributors

45. The opioid distributor defendants (“Opioid Distributors”) are: McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Drug Corporation.

46. At all relevant times, the Opioid Distributors have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs from non-medical purposes. The Distributors universally failed to comply with federal, state, and Commonwealth law. The Opioid Distributors are engaged in “wholesale distribution,” as defined under federal, state, and Commonwealth law. Plaintiffs allege the unlawful conduct by the Opioid Distributors is responsible for the volume of prescription opioids plaguing Plaintiffs’ communities.

McKesson Defendants

47. McKesson Corporation (“McKesson”) is a Delaware corporation with its principal place of business in San Francisco, California. At all relevant times, McKesson operated as a nationwide pharmacy wholesaler.

Cardinal Health Defendants

48. Cardinal Health, Inc. (“Cardinal”) is an Ohio corporation with its principal office in Dublin, Ohio. At all relevant times, Cardinal operated as a nationwide pharmacy wholesaler.

AmerisourceBergen Defendants

49. AmerisourceBergen Drug Corporation (“AmerisourceBergen”) is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. At all relevant times, AmerisourceBergen operated as a nationwide pharmacy wholesaler.

50. The data, which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA’s confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.^{17,18}

51. Consequently, Plaintiffs have named the three wholesaler distributors (i.e., AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation) which dominate 85% of the market share for the distribution of prescription opioids. The “Big 3” are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998)(describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors). Each have been

¹⁷ See Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit (“SARF”), FOI, Records Management Section (“SAR”), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23)(filed 01/06/14)(noting that ARCOS data is “kept confidential by the DEA”).

¹⁸ See Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, case 0:13-cv—02832-PAM-FLN, (Document 93)(filed 11/02/16)(“Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.”).

investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiffs have reason to believe each have engaged in unlawful conduct, which resulted in the diversion of prescription opioids into their communities and that discovery will likely reveal others who likewise engaged in unlawful conduct. Plaintiffs name each of the “Big 3” herein as defendants and place the industry on notice that Plaintiffs are acting to abate the public nuisance plaguing their communities. Plaintiffs will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

FACTUAL ALLEGATIONS

52. Before the 1990s, generally accepted standard of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients’ ability to function by overcoming pain, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

53. To take advantage of the lucrative market for chronic pain patients, each Defendant developed a well-funded marketing scheme based on deception. Each Defendant used both direct and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that benefitted not only themselves and the third-parties who gained legitimacy when Defendants repeated those statements, but also other Defendants and opioid manufacturers. Yet these statements were not only unsupported by or contrary to the scientific evidence, they were

also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

A. DEFENDENTS USED MULTIPLE AVENUES TO DISSEMINATE THEIR FALSE AND DECEPTIVE STATEMENTS ABOUT OPIOIDS

54. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in the United States. Defendants deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain.

1. Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids

55. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted and continues to conduct advertising campaigns touting the purported benefit of their branded drugs. For example, Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The amount included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

56. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like a construction worker and chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement. Purdue also ran a series of ads, called "Pain Vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading

representations in New York, but they may continue to disseminate in elsewhere in the United States.

57. Second, each Defendant promoted the use of opioids for chronic pain through “detailers” – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Defendants have not corrected this misinformation. Instead, each Defendant devoted and continues to devote massive resources to direct sales contracts with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10 million by Endo, and \$2 million by Actavis.

58. Defendants’ detailers have been reprimanded for their deceptive promotions. A July 2010 “Dear Doctor” letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that “[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian],” including the risk of “[m]isuse, [a]buse, and [d]iversion of Opioids” and, specifically, the risk that “Opioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.”

59. Defendants also identified doctors to serve, for payment, on their speakers’ bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; (3) an opportunity to promote the drug through the speaker to his or her peers. These

speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

60. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Defendants purchase, manipulate, and analyze some of the most sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Defendants *know* their detailing to doctors is effective.

61. Defendants employed the same marketing plans and strategies and deployed the same message nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

62. Defendants ensure marketing consistency nationwide through national and regional sales representatives training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed

talking points, sales messages, and slide decks, and supervisors rode along with them periodically to check on both their performance and compliance.

2. Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids

63. Defendants also deceptively marketed opioids through unbranded advertising – *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled their deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their “core messages” via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third parties.

64. Defendants also marketed through third party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

65. Defendants’ deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
“People who take opioids as prescribed usually do not become addicted.”	“All patients treated with opioids require careful monitoring for signs of abuse and addiction, since the use of opioid analgesic products carries the risk of addiction even under appropriate medical use.”

a. Key Opinion Leaders (“KOLs”)

66. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as “key opinion leaders” or “KOLs.”

67. Defendants paid KOLs to serve as consultants on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs’ professional reputations became dependent on continuing to promote pro-opioid message, even in activities that were not directly funded by Defendants.

68. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants have created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast,

Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

69. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guidelines recognizes that treatment guidelines can **"change prescribing practices."**

70. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants knew that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.¹⁹

71. Thus, even though some of the KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, these admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide in Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

¹⁹ See *In re Purdue Pharma L.P., Assurance of Discontinuance* ¶ 18, at 8 (N.Y. Att. Gen. Aug. 19, 2015)("[T]he website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost \$231,000, for speaker programs, advisory meetings, and travel costs, to 11 of the Advocates whose testimonials appeared on the site.").

72. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

(1) Russell Portenoy

73. Dr. Russell Portenoy, former chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

74. Dr. Portenoy was instrumental in opening the door for regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”/American Academy of Pain Medicine (“AAPM”) Guideline Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of American Pain Foundation (“APF”), an advocacy organization almost entirely funded by Defendants.

75. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcasted across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors feel very assured that that person is not going to become addicted.”²⁰

76. To his credit, Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that

²⁰ *Good Morning America Television Broadcast*, ABC News (Aug. 30, 2010).

less than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “de-stigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”²¹ Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”²²

(2) Lynn Webster

77. Another KOL, Dr. Lynn Webster, was the co-founder and Chief medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was president in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was a speaker at numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

78. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice’s Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster’s former patients at the Lifetree Clinic have died of opioid overdoses.

79. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-

²¹ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.

²² *Id.*

sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

80. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patients' Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors nationwide.

81. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should not be seen as warnings, but as indications of undertreated pain. In Dr. Weber's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."²³

b. Front Groups

82. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated

²³ John Fauber, *Networking Fuels Painkiller Boom*, Bangor Daily News (Feb. 19, 2012).

treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

83. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

84. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), American Society of Pain Education (“ASPE”), National Pain Foundation (“NPF”), and Pain & Policy Studies Group (“PPSG”).

(1) American Pain Foundation (“APF”)

85. The most prominent of Defendants’ Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, \$1.7 million.

86. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of

addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach nationwide.

87. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue), Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF’s board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

88. In 2009 and 2010, more than 80% of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

89. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus profitability of its sponsors. It was often called upon to provide “patient

representatives” for Defendants’ promotional activities, including for Purdue’s *Partners Against Pain* and Janssen’s *Let’s Talk Pain*. APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2011, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in nonprofit organizations that share [its] business interests.”

90. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund those activities and publications, knowing that drug companies would support projects conceived as a result of those communications.

91. APF assisted in other marketing projects for drug companies. One project funded by another drug company – *APF Reporter’s Guide: Covering Pain and Its Management* (2009) – recycled text that was originally created as part of the company’s training document.

92. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medication generally, the company representative responded, “I provided an advocacy grant to APF this year – this would be a very good issue on which to use some of that. How does that work?”

93. The close relationship between APF and the drug company highlighted in the previous paragraph was not unique, but mirrors relationships between APF and Defendants. APF’s clear lack of independence – in its finances, management, and mission – and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

94. Indeed the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist effective immediately."

(2) American Academy of Pain Medicine ("AAPM")

95. The American Academy of Pain Medicine, with the assistance, promoting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

96. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM described the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

97. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs,

and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”²⁴

98. AAPM’s staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

99. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors’ prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

100. In 1997, AAPM and the American Pain Society jointly issues a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until

²⁴ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), *available at* <http://www.medscape.org.viewartcile/500829>.

2011, and was taken down from the AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

101. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

102. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache and Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Mississippi during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

103. Defendants wildly referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

104. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF

project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Defendants determined would reduce prescribing.

B. DEFENDANTS' MARKETING SCHEME MISREPRESENTED THE RISKS AND BENEFITS OF OPIOIDS

105. To convince doctors and patients in the United States that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by or were contrary to scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

1. Defendants falsely trivialized and/or failed to disclose the known risks of long-term opioid use

106. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of

addiction probably were not addicted and, in any event, could be easily weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

107. Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

- a. Actavis's predecessor caused a patient education to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the Opioid medications that are prescribed for them."
- d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

- f. Janssen currently runs a website, Prescriberresponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction.” This publication is still available online.
- h. Detailers for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse deterrent formulations; and routinely did not correct the misrepresentations noted above.

108. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence” of the “possible harms of Opioids (including opioid use disorder [an alternative term for Opioid addiction]).” The Guideline points out that “Opioid pain medication use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases the risk for opioid use disorder.” (See Exhibit 1).

109. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’ and the opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal Opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to

patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [Opioids].”

110. The warnings on Defendants’ own FDA-approved drug labels caution that Opioids “expose users to risks of addiction, abuse and misuse, which can lead to overdose and death,” that the drugs contain “a substance with a high potential for abuse,” and that addiction “can occur in patients appropriately prescribed” opioids.

111. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.” Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State found that Endo had no evidence for that statement.²⁵ Consistent with this, Endo agreed not to “make statements that . . . opioids are generally non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however to make those statements in other States, including Mississippi.

112. Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants have called this phenomenon “pseudo addiction” – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and falsely claimed that pseudo addiction is substantiated

²⁵ See *Endo Health Solutions Inc., Assurance of Discontinuance* ¶ 20, at 6 (N.Y. Att. Gen. Mar. 1, 2016).

by scientific evidence. Some illustrative examples of these deceptive claims are described below:

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo addiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition which also remains available online, continues to falsely teach that pseudo addiction is real.
- b. Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “[P]seudo addiction . . . refers to patient behaviors that may occur when pain is undertreated Pseudo addiction is different from true addiction because such behaviors can be resolved with effective pain management.”
- c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudo addiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of “[drug seeking behaviors] in patients who have pain that has not been effectively treated.”
- e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role-play, a chronic pain patient with a history of drug abuse tells his doctor that he taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudo addiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats his patient by prescribing a high-dose, long acting opioid.

113. The 2016 CDC Guidelines rejects the concept of pseudo addiction. The Guidelines nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guidelines explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with

longer term use,” and that physicians should “reassess pain and function within 1 month” in order to decide whether to “minimize the risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”²⁶

114. Even one of the Defendants has effectively repudiated the concept of pseudo addiction. In finding that “[t]he pseudo addiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the State of New York, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the ‘pseudo addiction concept’ and acknowledging the difficulty in distinguishing ‘between addiction and ‘pseudo addiction.’” Consistent with this, Endo agreed not to “use the term ‘pseudo addiction’ in any training or marketing” in New York. Endo, however, remains free to do so in other States, including Mississippi.

115. Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants’ misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting an opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at

²⁶ CDC Guidelines for Prescribing Opioids for Chronic Pain – United States 2016, March 18, 2016. (available at: <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>).

high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts.

- b. Purdue sponsored a 2011 webinar, *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent “overuse of prescriptions” and “overdose deaths.”
- c. As recently as 2015, Purdue has represented in scientific conferences that “bad apples” patients – and not opioids – are the source of the addiction crisis and that once those “bad apples” are identified, doctors can safely prescribe opioids without causing addiction.

116. Once again, the CDC Guidelines confirms the falsity of these misrepresentations.

The Guideline notes there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the Guidelines recognizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [Opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

117. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

118. For example, A CME sponsored event by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days. And Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical

dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.

119. Defendants deceptively minimized the significant symptoms of opioid withdrawal – which as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guidelines recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiological response in patients exposed to opioids for more than a few days.” The Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize the symptoms and signs of opioid withdrawal” and to “pause and restart” tapers depending on the patient’s response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”²⁷

120. Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greatest risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors

²⁷ CDC Guidelines for Prescribing Opioids for Chronic Pain – United States 2016, March 18, 2016. (available at: <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>).

would have abandoned treatment when patients build up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

- a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon further information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options a Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.
- c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosage may be increased until "you are on the right dose of medication for your pain."
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was recently available on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased You won't 'run out' of pain relief."
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines by omitted any discussion of risks of increased opioid dosages.
- f. Purdue's *In the Face of Pain* website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymakers Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.
- h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the “oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,” see www.cpdd.org, challenging the correlation between opioid dosage and overdose.

121. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.” More specifically, the CDC explains “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC also states “there is an increased risk of opioid use disorder, respiratory depression, and death at higher dosages.” That is why the CDC advises doctors to “avoid increased dosages” above 90 morphine milligram equivalents per day.²⁸

122. The 2016 CDC Guidelines reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”

123. Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.²⁹ More specifically, Defendants have made misleading claims about the ability of their so-called abuse deterrent

²⁸ CDC Guidelines for Prescribing Opioids for Chronic Pain – United States 2016, March 18, 2016. (available at: <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>).

²⁹ Catherine S. Hwang, et al., *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA Intern. Med. 302-04 (Dec. 8, 2014).

opioid formulations to deter abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo’s design “would provide a reduction in oral, intranasal, or intravenous abuse.” The FDA has subsequently taken the extraordinary action of “request[ing] that Endo Pharmaceuticals remove . . . Opana ER . . . from the market.”³⁰ According to the FDA, Endo’s reformulation of Opana ER “made things worse”; “[P]ostmarketing data . . . demonstrate[s] a significant shift in the route of abuse of Opana ER from nasal to injection following the product’s reformulation.”³¹ Moreover, Endo’s own studies, which it fails to disclose, showed that Opana ER could still be ground and chewed.

124. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was “designed to be, or is crush resistant.” The State found these statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER.³² Similarly, the 2016 CDC Guidelines states that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies – even when they work – “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.”³³

125. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

³⁰ Maggie Fox, *FDA Asks Drug Company to Pull its Opioid Opana Because of Abuse*, NBCNews.com (June 9, 2017), <http://www.nbcnews.com/storyline/americas-heroin-epidemic/fda-asks-drug-company-pull-its-opioid-opana-because-abuse-n770121>.

³¹ *Id.*

³² See *Endo Health Solutions Inc., Assurance of Discontinuance* ¶ 20, at 6 (N.Y. Att. Gen. Mar. 1, 2016).

³³ CDC Guidelines for Prescribing Opioids for Chronic Pain – United States 2016, March 18, 2016. (available at: <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>).

2. Defendants grossly overstated the benefits of chronic opioid therapy

126. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guidelines make clear, there is “insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well controlled studies of opioids use longer than 12 weeks.” Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

127. For example, Defendants falsely claimed that long-term opioid use improved patients’ function and quality of life. Some illustrative examples are described below:

- a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements for opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- d. Purdue ran a series of advertisements for Oxycontin in 2012 in medical journals entitled “Pain Vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patient function.

- e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012.
- g. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improved depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.
- j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in "improving daily function, psychological health, and health related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.
- k. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

128. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded, "there is no good evidence that opioids improve pain or

function with long-term use, and . . . complete relief of pain is unlikely.”³⁴ The CDC reinforces this conclusion throughout its 2016 Guideline:

- “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . .”
- “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- “[E]vidence is limited or insufficient for improved pain or function with long term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”³⁵

129. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.”³⁶ As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

130. The 2016 Guideline was not the first time a federal agency repudiated Defendants’ claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described above, that “[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”³⁷ And in 2008, the FDA sent a

³⁴ CDC Guidelines for Prescribing Opioids for Chronic Pain – United States 2016, March 18, 2016. (available at: <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>). (emphasis added).

³⁵ *Id.*

³⁶ *Id.*

³⁷ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comme’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm>.

warning letter to an opioid manufacturer, making it clear “that [the claims that] patients who are treated with the drug experience and improvement in their function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

131. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

132. In addition, Purdue misleadingly promoted Oxycontin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. According to Purdue’s own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial number” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of 12 hours of relief false and deceptive, it

also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

133. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

134. Front Groups supported by Purdue likewise echoed these representations. For example, as an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain, and the Ohio Pain Initiative in support of Purdue, those amici represented:

Oxycontin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, Oxycontin has been a miracle medication.³⁸

3. Defendants also engaged in other unlawful, unfair, and fraudulent misconduct

135. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the

³⁸ See Reply Br. of Amicus Curiae American Pain Foundation, The National Foundation for the Treatment of Pain, and the Ohio Pain Initiative supporting Appellants, 2004 WL 1637768, at *4.

FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

136. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KILs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.
- Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- In December 2011, Cephalon widely disseminated a journal supplement entitled “*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTQ)*” to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

137. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

138. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue had failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite the knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as “an organized drug ring.” In doing so, Purdue protected its own profits at the expense of public health and safety.

139. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing.³⁹ Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

³⁹ See *Purdue Pharma L.P., Assurance of Discontinuance* ¶ 9-15 (N.Y. Att. Gen. Aug. 19 2015).

140. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

C. DEFENDANTS TARGETED SUSCEPTIBLE PRESCRIBERS AND VULNERABLE PATIENT POPULATIONS

141. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States, including Mississippi. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

142. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking Opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions.⁴⁰ The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors

⁴⁰ CDC Guidelines for Prescribing Opioids for Chronic Pain – United States 2016, March 18, 2016. (available at: <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>).

use “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

D. ALTHOUGH DEFENDANTS KNEW THAT THEIR MARKETING OF OPIOIDS WAS FALSE AND DECEPTIVE, THEY FRAUDULENTLY CONCEALED THEIR MISCONDUCT

143. Defendants, both individually and collectively, made, promoted and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical evidence over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious outcomes. The FDA and other regulators warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and details – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants’ misrepresentations, and Endo and Purdue have recently entered into agreements prohibiting them from making in New York some of the same misrepresentations described in this Complaint.⁴¹

144. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front

⁴¹ See *Purdue Pharma L.P., Assurance of Discontinuance* (N.Y. Att. Gen. Aug. 19 2015) and *See Endo Health Solutions Inc., Assurance of Discontinuance* (N.Y. Att. Gen. Mar. 1, 2016).

Groups and KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

145. Defendants also never disclosed their role shaping, editing, and approving the content of information and materials disseminated by these third parties such as KOLs and Front Groups. Defendants exerted considerable influence on these promotional and "educational" materials in e-mails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Defendants, including Purdue and Janssen, ran similar website that masked their own direct role.

146. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning of or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions.

147. Thus, Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that Plaintiffs now assert. Plaintiffs did not know or have reason to know the existence and/or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier or through the exercise of reasonable diligence.

E. BY INCREASING OPIOID PRESCRIPTIONS AND USE, DEFENDANTS' DECEPTIVE MARKETING SCHEME HAS FUELED THE OPIOID EPIDEMIC AND DEVASTATED COMMUNITIES

148. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that four out of ten were not told opioids were potentially addictive.⁴²

149. Defendants' deceptive marketing scheme caused and continues to cause doctors to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

150. Defendants' deceptive marketing has caused and continued to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

⁴² Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), available at <http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent-opioid-addiction>.

151. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the United States, including Mississippi. In August 2016, the United States Surgeon General at the time, Vivek Murthy, published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

152. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "Opioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." *Patients receiving prescription opioids for chronic pain account for the majority of overdoses.* For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

153. Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers, or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

154. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. Opioids are by far the most commonly prescribed class of substances in Mississippi. In 2017, providers wrote 92.9 opioid prescriptions for every 100 persons, compared to the average U.S. rate of 58.7 prescriptions. This was among the top five rates in the United States that year (CDC); however, it was also the lowest rate in the state since data became available in 2006.⁴³ In 2017, there were more than 70,200 drug overdose deaths in the U.S. – an age-adjusted rate of 21.7 per 100,000 persons. Among these, 47,600 involved opioids. The sharpest increase occurred among deaths involving fentanyl and fentanyl analogs (other synthetic narcotics) with more than 28,400 overdose deaths in 2017.⁴⁴ The age-adjusted rate of drug overdose deaths has not significantly changed in Mississippi over the past several years. In 2017, there were 12.2 drug overdose deaths per 100,000 persons.⁴⁵ From 2011 to 2017, deaths involving opioids (including prescription, fentanyl, heroin, and methadone) increased by 136.8%, and in 2017, accounted for 52.0% of all drug related over dose deaths.⁴⁶

155. Opioid-related emergencies are rising at such a rapid pace that cities and counties in Mississippi are unable to keep up logistically and financially. In 2017, the total number of Emergency Department (ED) visits in Mississippi totaled 4,036, a 7.4% increase since 2016 out of which 865 can be attributed to opioid related overdose events.⁴⁷ This has amounted to a total cost of \$23,425,614, a 12.9% increase since 2016 that carries a \$64,180 charge per day.⁴⁸

⁴³ National Institute on Drug Abuse (NIDA), *Mississippi Opioid Summary*, Last updated May 2019 <https://www.drugabuse.gov>.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ Mississippi State Department of Health, *Drug Overdose Deaths In Mississippi, 2011-2017*. Mississippi's Drug Epidemic Surveillance System. Epidemiological Report, 1/22/2019. https://msdh.ms.gov/msdhsite/_static/resources/7980.pdf.

⁴⁷ Mississippi State Department of Health, *The Mississippi Opioid Epidemic: Data and Actions At A Glance, 2016 and 2017*. The Mississippi Opioid Epidemic Project, 9/22/2018. https://msdh.ms.gov/msdhsite/index.cfm/44,7821,382.pdf/DataBrief_opioid_actions_2016-2017.pdf.

⁴⁸ *Id.*

156. This increase correlates to hospitalizations as well. In 2017, there were 8,022 total hospitalizations, an 11.7% increase since 2016, with 890 hospitalizations specifically for opioid related overdoses.⁴⁹ This amounted to a total cost of \$322,408,631, a 17.1% increase since 2016 and carries an \$883,311 charge per day.⁵⁰

157. Looking back even further to 2014, this upward trend has continued since 2014. According to the latest Mississippi State Department Health Department data, hospitalizations have increased by 72.7% and Emergency Department visits have increased even more by 75.3% over the same time period.⁵¹

158. Even more troubling, the 2016 data shows that even though prescriptions for opioid pain medications in Mississippi has seen a 4.1% decrease since 2012, Mississippi has seen an 8.6% increase in Morphine Milligram Equivalents as well as a 6.1% increase in the total days of opioid supply.⁵²

159. Defendants' deceptive marketing scheme has also had a significant detrimental impact on children in Mississippi. The overprescribing of opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household. Furthermore, the overprescribing of opioids has "caused the number of children in foster care to increase,

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ Mississippi State Department of Health, *Opioid-Related Hospitalizations And Emergency Department Visits, Mississippi, 2014-2017*. The Mississippi Opioid Epidemic Project, Epidemiological Report; 9/24/2018. https://msdh.ms.gov/msdhsite/_static/resources/7823.pdf.

⁵² *Data and Actions At A Glance, 2016 and 2017*. The Mississippi Opioid Epidemic Project, 9/22/2018. https://msdh.ms.gov/msdhsite/index.cfm/44,7821,382,pdf/DataBrief_opioid_actions_2016-2017.pdf.

prompting the hiring of an estimated 150 more social workers to handle the influx of children” and “has increased its foster care entries by 30%.”⁵³

160. The overprescribing of opioids for chronic pain caused by Defendants’ deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Mississippi who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome (“NAS”). These infants face painful withdrawal and may suffer long-term neurological and cognitive impacts. Babies with NAS typically require extensive hospital stays as they withdraw. “The number of infant hospitalizations related to maternal use of narcotics (e.g., opioids) in Mississippi increased by 46.3% between 2010 and 2015. The diagnostic code ‘narcotics’ was used to record hospitalizations for Opioid exposed infants because presently there is no Opioid-specific ICD-10-CM diagnostic code.”⁵⁴

161. The number of emergency medical services (“EMS”) runs for suspected opioid related overdoses have also increased. As that has occurred, the utilization of Naloxone (“Narcan”), a drug used to reverse opiate induced overdoses, has risen dramatically. In, 2017, according to the Mississippi State Department of Health, there were more than 1,800 doses of Narcan given to patients by licensed emergency services providers.⁵⁵

162. John Dowdy, Mississippi’s State Bureau of Narcotics Director, sees the effect of the opioid crisis first hand and states, “We keep seeing more and more people that are dying from this epidemic. Just this year alone in Hinds County, the drug overdose deaths have

⁵³ Brett Thompson-May, *Children of the Opioid Epidemic*. Healthmediapolicy.com, July 5, 2018. <https://healthmediapolicy.com/2018/07/05/children-of-the-opioid-epidemic/>.

⁵⁴ Mississippi State Department of Health, *Neonatal Hospitalizations Related to Substance Use in Mississippi: Surveillance Report, 2010-2017*. The Mississippi Drug Epidemic Surveillance System, Epidemiological Report 5/24/2019. https://msdh.ms.gov/msdhsite/_static/resources/8164.pdf.

⁵⁵ Mark Rigsby, *EMS In Mississippi Giving Life-Saving Drug Overdose Antidote Frequently*, mpbonline.org, 12/19/2017. <http://www.mpbonline.org/blogs/news/2017/12/19/ems-in-mississippi-giving-life-saving-drug-overdose-antidote-frequently/>.

quadrupled. If folks don't understand that there's a problem at this point, I don't know what rock they've been living under."⁵⁶

163. Defendants' creation, through false and deceptive misrepresentations and other unlawful and unfair concert, of a virtually limitless opioid market has significantly harmed Plaintiffs throughout the United States, including Mississippi. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.⁵⁷

164. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including: doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their places of employment.

165. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. In fact, a 2005 study by The Center on Addiction and Substance Abuse at Columbia University revealed that, by that time, 20.9% of pharmacies nationwide had stopped stocking certain medications such as OxyContin and Percocet, in order to protect themselves from robbery. The ongoing diversion of prescription narcotics creates a lucrative marketplace.⁵⁸

⁵⁶ *Id.*

⁵⁷ Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care 5 (Apr. 19, 2013) ("The most common source of abused [Opioids] is, directly or indirectly, by prescription."), available at <http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers>.

⁵⁸ Times Record. *Narcan's Importance Grows As Prescription Drug Abuse Increases*. May 22, 2016 (confirming that opioids are "hot on the black market").

166. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription drugs. Individuals who are addicted to prescription opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high.⁵⁹

167. The costs and consequences of opioid addiction are staggering. Prescription opioid misuse, abuse, and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness, and incarceration. This results in instability in communities already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers, and law enforcement.

168. Defendants knew and should have known about these harms that their deceptive conduct has caused. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

⁵⁹ Kate Jordan. *Police: Heroin Becoming More Prevalent In Fort Smith Region*. (“One of the reasons heroin is making a come-back is because people are so addicted to pharmaceuticals – opiates and opioids, and heroin is cheaper.” (quotation omitted)).

169. Defendants' are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on medical evidence and their own labels.

170. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe: Namely, those opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

171. While the use of opioids has taken an enormous toll on Plaintiffs, Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenues, and profits from the false and deceptive misrepresentations and other unlawful and unfair conduct described above.

CAUSES OF ACTION

COUNT I PUBLIC NUISANCE (Against all Defendants)

172. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

173. Defendants are liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to, Plaintiffs' injury. *See* Restatement Second, Torts § 821B.

174. Mississippi has declared that Mississippi consumers of prescription drugs will be better assured of safe and effective prescription drug products if similarly situated Plaintiffs join with the instant Plaintiffs to require the licensure of all persons who operate facilities from which they engage in the wholesale distribution of prescription drugs. Further, the legislature has declared that it is the furthest intent of the General Assembly to promote the safety and effectiveness of prescription drug products by requiring all persons who operate facilities within the United States from which they engage in the wholesale distribution and/or manufacture of prescription drugs to secure a license and meet minimum quality assurance and operational standards as required by the Act.

175. By causing dangerous addictive drugs to flood the communities of the United States, including Mississippi, and to be diverted for illicit purposes, in contravention of Federal and State law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the Plaintiffs to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by the Defendants' diversion of dangerous drugs has caused substantial annoyance, inconvenience, and injury to the public.

176. By selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific, or industrial purpose, Defendants have committed a continuing course of conduct that injuriously affects the safety, health, and morals of the Plaintiffs.

177. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the Plaintiffs.

178. Plaintiffs allege that Defendants wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

179. The Defendants have intentionally and/or unlawfully created an absolute nuisance.

180. The Plaintiffs have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

181. Defendants intentionally, unlawfully, and recklessly manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing widespread distribution of prescription opioids in and/or to Plaintiffs, resulting in addiction and abuse, an elevated level of crime, death and injuries, a higher level of fear, discomfort and inconvenience, and direct costs to Plaintiffs.

182. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Plaintiffs.

183. Defendants have unlawfully and/or intentionally manufactured and/or distributed opioids and/or caused opioids to be manufactured and/or distributed without maintaining effective controls against diversion. Such conduct was illegal. Defendants' failures to maintain

effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

184. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

185. Defendants' conduct in illegally manufacturing and/or distributing and/or selling prescription opioids, or causing such opioids to be distributed and/or sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally by Plaintiffs is of a continuing nature.

186. Defendants' actions have been of a persistent and continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

187. A violation of any rule or law controlling the manufacture and/or distribution of a drug of abuse in the United States, including Mississippi, is a public nuisance.

188. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

189. Defendants' ongoing and repeated course of conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in the United States, including Mississippi, will be diverted, leading to abuse, addiction, crime, and public health costs.

190. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subject to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

191. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

192. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

193. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal law.⁶⁰

194. Defendants' conduct in manufacturing, marketing, distributing, and selling prescription opioids which the Defendants know, or reasonably should know, will likely be diverted for non-legitimate, non-medical use, creates a strong likelihood that these illegal distributions of opioids will cause and have caused death and injuries to Plaintiffs and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

195. It is, or should be, reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to Plaintiffs, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

⁶⁰ See, e.g., 21 U.S.C. § 812 (b)(2).

196. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in the United States, including Mississippi, not only cause deaths and injuries, but also creates a palpable climate of fear among residents where opioid diversion, abuse, addiction are prevalent and where diverted opioids tend to be used frequently.

197. Defendants' conduct makes it easier for persons to divert prescription opioids constituting a dangerous threat to the public.

198. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid manufacture and/or distribution, without Defendants' actions, opioid use would not have become so widespread, and addiction that now exists would have been averted.

199. The presence of diverted prescription opioids in the United States, including Mississippi, and the consequence of prescription opioids having been diverted in the United States, including Mississippi, proximately results in and/or substantially contributing to the creation of significant costs to the Plaintiffs in order to enforce the law, equip its police force, and treat the victims of opioid abuse and addiction.

200. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make the nation's communities a safer place to live.

201. Defendants' conduct is a direct and proximate cause of and/or substantial contributing factor to opioid addiction and abuse in the United States, including Mississippi, costs borne by Plaintiffs, and a significant and unreasonable interference with public health,

safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

202. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety, and welfare of Plaintiffs, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiffs have a clearly ascertainable right to abate conduct that perpetuates this nuisance.

203. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in the nation's communities, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully manufactured and/or distributed opioids or caused opioids to be manufactured and/or distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids, or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

204. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the

opioids would be diverted, and create an opioid abuse nuisance in the United States, including Mississippi.

205. Defendants' actions also created a qualified nuisance. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

206. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

207. The damages available to the Plaintiffs include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance, which the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiffs seek all damages flowing from Defendants' conduct. Plaintiffs further seek to abate the nuisance and harm created by Defendants' conduct.

208. As a direct result of Defendants' conduct, the Plaintiffs have suffered actual ongoing injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The Plaintiffs here seek recovery for its own harm, medical treatment, funeral expenses and continuing medical care as well as other damages appropriate up and to including punitive damages.

209. The Plaintiffs have sustained specific and special injuries because their damages include, *inter alia*, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

210. The Plaintiffs further seek to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

211. Plaintiffs seek all the legal and equitable relief as allowed by law, including *inter alia* abatement, compensatory damages, and punitive damages from the Defendants for the creation of a public nuisance, attorney fees and costs, and pre- and post- judgment interest.

212. Defendants' intentional and unlawful actions and omissions and unreasonable interference with the right common to the public are of a continuing nature.

213. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the nation's communities. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under Federal and State law as substances posing a high potential for abuse and severe addiction. Defendants created an absolute nuisance. Defendant's actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

214. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is not limited to the following:

- a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths;

- b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers;
- c. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;
- d. Even those residents of the United States who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gatekeeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids;
- e. The opioid epidemic has increased health care costs;
- f. Employers have lost the value of productive and healthy employees;
- g. Defendants' conduct created an abundance of drugs available from criminal use and fueled a new wave of addiction, abuse, and injury;
- h. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result;
- i. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement;
- j. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the nation's communities;
- k. Defendants' interference with the comfortable enjoyment of life in communities is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions;
- l. The Plaintiffs have sustained specific and special injuries because its damages include *inter alia* health services and law enforcement expenditures, as described in this Complaint;

- m. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations; and
- n. Plaintiffs seek all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.
- o. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor and Manufacturer Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT II
RACKETEER INFLUCENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1961, et seq.
(Against all Defendants)

215. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

216. Plaintiffs bring this Count on behalf of itself against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purpose of this Count, the "RICO Defendants").

217. Each Defendant is associated with an enterprise, which affects interstate commerce for purposes, which include the illegal distribution of opioids. As explained herein, each Defendants conducted or participated in the enterprise's affairs through commission of criminal offenses which constitute a pattern of racketeering activity.

218. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. §

1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

219. Section 1962(c) of RICO makes it unlawful “for any person employed by or commerce with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity or collection of unlawful debt.”⁶¹

220. Defendant corporations are “persons” within the meaning of 18 U.S.C.A. § 1961(3) which conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C.A. § 1962.⁶²

221. The term “enterprise” is defined as including “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.”⁶³ The definition of “enterprise” in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section “describes two separate categories of associations that come within the purview of an ‘enterprise’ – the first encompassing organizations such as corporations, partnerships, and other ‘legal entities,’ and the second covering ‘any union or group of individuals associated in fact although not a legal entity.’”⁶⁴ The second category is not a more generalized description of the first. *Id.*

222. The Plaintiffs were injured in its business or property as a result of each Defendant’s wrongful conduct and is a “person” who can bring an action for violation of section 1962, as that term is defined in 18 U.S.C.A. § 1961(3). “Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefore in any

⁶¹ 18 U.S.C. § 1962(c); *United States v. Turkette*, 452 U.S. 576, 580 (1981).

⁶² *Accord In re ClassicStar Lease Litig.*, 727 F.3d at 490-494 (6th Cir. 2013).

⁶³ 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009).

⁶⁴ *Turkette*, 452 U.S. at 577.

appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney fee”⁶⁵

223. Each Defendant conducted and participated in the conduct of the affairs of each Defendant’s Opioids Marketing Enterprise through a pattern of racketeering activity, which violates 18 U.S.C.A. § 1962(c).

224. Regardless of any licenses or registrations held by Defendants to distribute dangerous and harmful drugs, their conduct was not "lawful." Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

225. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As “registrants,” the RICO Defendants operated and continue to operate within the “closed-system” created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the “CSA”). The CSA restricts the RICO Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

226. The closed-system created by the CSA, including the establishment of quota, was

⁶⁵ 18 U.S.C.A. § 1964. *See Plaintiff of Oakland v. City of Detroit*, 866 F.2d 839 (6th Cir. 1989)(Plaintiff was “person” with standing to bring RICO claim), *cert. den.*, 497 U.S. 1003 (1990)).

specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from “legitimate channels of trade” to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances].”⁶⁶

227. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systemically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.⁶⁷ As discussed in detail below, through the RICO Defendants’ scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers, which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.⁶⁸ In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market, which allowed them to generate obscene profits.

228. Defendants illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to as the “Opioid Diversion Enterprise”), whose purpose was to engage in the unlawful sales of opioids, deceive the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants’ scheme

⁶⁶ 1970 U.S.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

⁶⁷ 21 U.S.C. § 823(a)(1); 21 C.F.R. § 1301.74(b)-(c).

⁶⁸ 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. It is a reasonable consequence of the prescription opioid addiction epidemic, that as a direct result of the RICO Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiffs are entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

229. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")⁶⁹ is a distinct legal entity that satisfies the definition of a RICO enterprise. The HAD is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

230. On information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

231. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO

⁶⁹ Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), <https://www.healthcaredistribution.org/about/had-history>.

enterprise.

232. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

A. THE OPIOID DIVERSION ENTERPRISE

233. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to the public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.⁷⁰ The CSA and its implementing regulations created a closed-system of distributions for all controlled substances and listed chemicals.⁷¹ Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.⁷² As reflected in comments from United States Senators during deliberation of the CSA, the “[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls.”⁷³ Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.”⁷⁴ Moreover, the closed-system was

⁷⁰ Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr.*, Attorney General, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

⁷¹ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

⁷² *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801 (20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

⁷³ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970).

⁷⁴ See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.⁷⁵ All registrants - - manufacturers and distributors alike - - must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.⁷⁶ When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.⁷⁷ The result is the scourge of addiction that has occurred.

234. In 2006 and 2007 the DEA issued multiple letters to the Distributor Defendants reminding them of their obligations to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.⁷⁸ The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to “know their customers.”⁷⁹

235. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.”⁸⁰ When

⁷⁵ See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, July 18, 2012 (available at <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>).

⁷⁶ *Id.*

⁷⁷ Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder Jr.*, Attorney General, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

⁷⁸ Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).

⁷⁹ Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).

⁸⁰ 1970 U.S.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;
- d. An applicant's production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.⁸¹

236. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.⁸²

237. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

238. The opioid epidemic has its origins in the mid-1990s when, between 1997 and

⁸¹ See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

⁸² *Id.* (citing 21 U.S.C. 842(b)).

2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.⁸³ On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.⁸⁴

239. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. It has been conducting business uninterrupted since its genesis. But, it was not until recently that the United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

240. At all relevant times, the Opioid Diversion Enterprise:

- a. Had an existence separate and distinct from each of the RICO Defendants;
- b. Was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged;
- c. Was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants;
- d. Characterized by interpersonal relationships among the RICO Defendants;
- e. Had sufficient longevity for the enterprise to pursue its purpose; and
- f. Functioned as a continuing unit.⁸⁵

241. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid

⁸³ Keyes KM, Cerda M, Brady JE, Havens JR, Galea S. Understanding the rural – urban differences in nonmedical prescription opioid use and abuse in the United States. *Am. J. Public Health.* 2014;104(2):e52-9.

⁸⁴ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, *The Center for Public Integrity* (September 19, 2017, 21:01a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

⁸⁵ *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009).

Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

242. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.⁸⁶ The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiffs are informed and believe the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

243. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating Federal and State laws requiring the maintenance of effective controls against the diversion of prescription opioids, and the

⁸⁶ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, mar. 6, 2017, https://www.washingtonpost.com/investigation/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-ble9-a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->

identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

244. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the state and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

245. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

246. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in, and are members of, the enterprise, they each have a

separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

247. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

248. The Pain Care Forum (“PCF”) has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped Federal, and State policies regarding the use of prescription opioids for more than a decade.

249. Then Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”⁸⁷ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.⁸⁸

250. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.⁸⁹ In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company of Janssen

⁸⁷ Matthew Perrone, Pro-Painkiller echo chamber policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

⁸⁸ *Id.*

⁸⁹ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>.

Pharmaceuticals), Actavis (*i.e.*, Allergan), and Teva (the parent company of Cephalon).⁹⁰ Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.⁹¹ Plaintiffs are informed and believes that the Distributor Defendants participated directly in the PCF as well.

251. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

252. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

253. Second, the HDA - - or Healthcare Distribution Alliance - - led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the

⁹⁰ *Id.* Plaintiffs are informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

⁹¹ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://healthcaredistribution.org/about/executive-committee>.

Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.⁹² And, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

254. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at the HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”⁹³ Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

255. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.⁹⁴ A “senior company executive” must sign the manufacturer membership application” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its

⁹² Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/membership/manufacturer>.

⁹³ Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>.

⁹⁴ Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.⁹⁵

256. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”⁹⁶
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas focus within pharmaceutical distribution includes information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributors and manufacturer members.⁹⁷
- c. Health, Beauty and Wellness Committee: “This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain.” Participation in this committee includes distributors and manufacturer members.⁹⁸
- d. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributors and manufacturer members.⁹⁹
- e. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.¹⁰⁰

⁹⁵ *Id.*

⁹⁶ Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/councils-and-committees>.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

- f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁰¹
- g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁰²
- h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.¹⁰³
- i. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation includes Distributor and Manufacturer Members.¹⁰⁴
- j. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise’s organization.

257. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”¹⁰⁵ The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”¹⁰⁶ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017) <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers>.

¹⁰⁶ *Id.*

is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.¹⁰⁷

258. Third, the RICO Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

259. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.¹⁰⁸ As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.¹⁰⁹ On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.¹¹⁰ The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

¹⁰⁷ 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed of September 14, 2017), <https://www.healthcaresitribution.org/events/2015-distributors-management-conference>.

¹⁰⁸ Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_=b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letter from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letters from Sen. Claire McCaskill, (March 28, 2017), <https://mccaskill.senate.gov/opioid-investigation>; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), <http://www.purduepharma.com/payers/managed-markets/>.

¹⁰⁹ *Id.*

¹¹⁰ Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2107), <https://www.healthcaresitribution.org/resources/webinar-leveraging-edi>.

260. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiffs are informed and believe that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiffs are informed and believe that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

261. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sales of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants was in communication and cooperation.

262. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum - - whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."¹¹¹ And, from 2006 to 2016 the Distributors and Manufacturers

¹¹¹ Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

worked together through the Pain Care Forum to spend over \$740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.¹¹²

Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.¹¹³

263. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiffs are informed and believe that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

264. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal, and State obligations to identify, investigate and report suspicious orders or opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

265. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

266. Defendants disseminated false and misleading statements to the public claiming that they were with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

¹¹² *Id.*

¹¹³ HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/had-history>.

267. Defendants paid nearly \$800 million dollars to influence Federal, and State governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

268. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

269. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."¹¹⁴

270. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiffs are informed and believe that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiffs are informed and believe that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger

¹¹⁴ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, mar. 6, 2017, https://www.washingtonpost.com/investigation/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-ble9-a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->

volumes.

271. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the RICO Defendants.

272. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.¹¹⁵ On information and belief, the “know your customer” questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

273. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012¹¹⁶ and 117 recommended decision in registrant actions from The

¹¹⁵ Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, 9available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

¹¹⁶ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, The Drug Enforcement Administration’s Adjudication of Registrant Actions 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders - - all for failure to report suspicious orders.¹¹⁷

274. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the Federal and State Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

275. The RICO Defendants worked together to control the flow of information and influence Federal and State governmental and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

276. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including

¹¹⁷ *Id.*

on the councils, committees, task forces, and working groups;

- c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioid prescriptions filled by the Distributor Defendants;
- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendant's sales information;
- e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."¹¹⁸;
- f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- g. The Manufacturer Defendants used the Distribution Defendants' sales information and the data from QuintileIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

277. The scheme devised and implemented by the RICO Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

¹¹⁸ Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew, Los Angeles Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

C. PATTERN OF RACKETEERING ACTIVITY

278. The RICO Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 § 1343); and 18 U.S.C. § 1961(D) by felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), punishable under any law of the United States.

1. The RICO Defendants engaged in mail and wire fraud

279. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud Federal, and State regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

280. The RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

281. The RICO Defendants used, directed the use of, and/or caused to be used,

thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

282. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

283. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but not limited to:

- a. Mail Fraud: The Rico Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

284. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the Pain Care Forum;
- m. Payments to Defendants' trade organizations, like HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacturer and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

285. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and

released documents by mail or by private or interstate carrier, shipments or prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

- a. Purdue Manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.
- b. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.
- c. Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.
- d. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.
- e. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.
- f. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.
- g. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percocet, and Zydene. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.
- h. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.
- i. The Distributor Defendants shipped Actavis' prescription opioids throughout this jurisdiction.
- j. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone.
- k. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

286. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

287. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all Federal and State regulations regarding the identification and reporting of suspicious orders of prescription opioids.

288. Plaintiffs are also informed and believe that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

289. The RICO Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

290. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their Federal and State obligations to identify and report suspicious orders of prescription opioids to divert into the illicit drug market. The RICO Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

291. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to

Defendants' books and records. But, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

292. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and/or minimize the losses for the RICO Defendants.

293. The RICO Defendants aided and abetted others in the violation of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

294. The RICO Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the RICO Defendants were filling on a daily basis - - leading to the diversion of a tens of millions of doses of prescription opioids into illicit market.

295. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

296. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

297. As described herein, the RICO Defendants engaged in a pattern of related and

continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

298. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants while Plaintiffs were left with substantial injury from the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

299. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

300. The pattern of racketeering activity alleged is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

301. Many of the precise dates of the RICO Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

302. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in the United States, including this

jurisdiction, and the Plaintiffs. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in the United States, including this jurisdiction. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacturer and distribution of those products. The Defendants were also aware that Plaintiffs in the United States, including this jurisdiction, rely on Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

303. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

304. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiffs by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

305. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

2. The RICO Defendants manufactured, sold and/or dealt in controlled substances and their crimes are punishable as felonies

306. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the

Controlled Substance Act), punishable under any law of the United States.

307. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony.¹¹⁹

308. Each of the RICO Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant.¹²⁰

309. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

310. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

¹¹⁹ 21 U.S.C. § 483(d)(1).

¹²⁰ 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

311. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay.

312. \$150 million and have some of its DEA registrations suspended on a staggered basis. The Settlement was finalized on January 17, 2017.¹²¹

313. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.¹²² The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."¹²³ Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussions of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."¹²⁴

¹²¹ McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Release, (January 17, 2017), <http://www.mckesson.com/about-mckesson/newsroom/press-release/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/>.

¹²² Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew, Los Angeles Times, (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

¹²³ *Id.*

¹²⁴ *Id.*

314. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.¹²⁵ After six years of DEA investigations, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida by they had no duty to report it.¹²⁶

315. Plaintiffs are informed and believe that the foregoing examples reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.¹²⁷

316. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

317. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by

¹²⁵ Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

¹²⁶ *Id.*

¹²⁷ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

this Court.

318. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

319. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in the United States, including this jurisdiction, and the Plaintiffs. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regards to the effect such behavior would have on the citizens of the United States, including this jurisdiction. The Defendants were aware that Plaintiffs rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

320. Each Defendant knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including the distribution of dangerous and harmful drugs to persons, including minors, in violation of federal law, 21 CFR 1301.74(b) at retail pharmacies, hospitals, and other health care facilities throughout the United States.

321. Each Defendant knowingly engaged in, attempted to engage in, conspired to engage in, or solicited another person to engage in racketeering activity, including thousands of separate instances of use of the United States Mail or interstate wire facilities in furtherance of each Defendants' unlawful Opioids Diversion Enterprise. Each of these fraudulent mailings and

interstate wire transmissions constitutes racketeering activity. Each Defendant specifically intended to obtain money by means of false pretenses, representations, and promises, and used the mail and interstate wires for the purpose of executing this scheme; specifically, each Defendant communicated with its respective retail pharmacy customers via wire and used the mail to receive orders and sell drugs unlawfully. Any violation of the mail or wire fraud statutes is defined as “racketeering activity.”¹²⁸

322. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiffs by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

323. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES

324. The RICO Defendants’ violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs to be injured because Plaintiffs paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

325. Plaintiffs’ injuries were proximately caused by Defendant’s racketeering activities. But for the RICO Defendants’ conduct, Plaintiffs would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

326. Plaintiffs’ injuries were directly caused by the RICO Defendants’ racketeering activities.

¹²⁸ 18 U.S.C. § 1961(1)(B).

327. Plaintiffs were most directly harmed and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.

328. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, a civil penalty of up to one hundred thousand dollars, forfeiture as deemed proper by the Court, attorney fees and costs¹²⁹ and expenses of suit and pre- and post-judgment interest.

COUNT III
RACKETEERING INFLUENCED AND CORRUPT ORGANIZATIONS ACT
(RICO) 18 U.S.C. 1962(d), et seq.
(Against all Defendants)

329. Plaintiffs hereby incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows.

330. Plaintiffs bring this claim on their own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for “any person to conspire to violate” Section 1962(d), among other provisions.¹³⁰

331. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

¹²⁹ 18 U.S.C. § 1964(c).

¹³⁰ 18 U.S.C. § 1962(d).

A. THE OPIOID DIVERSION ENTERPRISE

332. For efficiency and avoiding repetition, for purposes of this claim, Plaintiffs incorporate by reference the paragraphs set out above concerning the “Opioid Diversion Enterprise.”

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

333. For efficiency and avoiding repetition, for purposes of this claim, Plaintiffs incorporate by reference the paragraphs set out above concerning the “Conduct of the Opioid Diversion Enterprise.”

C. PATTERN OF RACKETEERING ACTIVITY

334. For efficiency and avoiding repetition, for purposes of this claim, Plaintiffs incorporate by reference the paragraphs set out above concerning the “Pattern of Racketeering Activity.”

D. DAMAGES

335. The RICO Defendants’ violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs’ injury because Plaintiffs paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

336. Plaintiffs’ injuries were proximately caused by the RICO Defendants’ conspiracy to violate Section 1962(c). But for the RICO Defendants’ conduct, Plaintiffs would not have paid expenditures required as a result of the plague of drug-addicted residents.

337. Plaintiff’s injuries and those of her citizens were directly caused by the RICO Defendants’ conspiracy to violate Section 1962(c).

338. Plaintiffs were most directly harmed and there are no other Plaintiffs better suited

to seek a remedy for the economic harms at issue here.

339. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post- judgment interest.

COUNT IV
FRAUD AND FRAUDULENTLY MISREPRESENTATION
(Against all Defendants)

340. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth here, and further allege as follows:

341. Defendants violated their general duty not to actively deceive, and have made knowingly false statements and have omitted and/or concealed information, which made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

342. As alleged herein, Defendants made false statements regarding their compliance with Federal and State law, regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

343. As alleged herein, the Distributor and Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

344. As alleged herein, Defendants knowingly and/or intentionally made representations there were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the

falsity of their representations, and did so with the intent of misleading Plaintiffs, Plaintiffs' communities, the public, and persons on whom Plaintiffs relied.

345. These false representations and concealments were reasonably calculated to deceive Plaintiffs and the physicians who prescribed opioids. The false representations and concealments were made with the intent to deceive these persons, to rely on these false representation and concealments and act accordingly, and in fact deceived these persons and Plaintiffs.

346. Plaintiffs and their physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

347. Plaintiffs justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. Plaintiffs' injuries were proximately caused by this reliance.

348. The injuries alleged by Plaintiffs herein were sustained as a direct and proximate cause of Defendants' fraudulent conduct.

349. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment.

350. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor and Manufacturer Defendants, attorney fees and costs, and pre- and post- judgment interest.

COUNT V
VIOLATION OF MISSISSIPPI UNFAIR AND
DECEPTIVE TRADE PRACTICES ACT
MISS. CODE ANN. § 75-24-1, et seq.
(Against All Defendants)

351. Plaintiffs repeat and reallege each of the above allegations as if fully set forth again.

352. Defendants' conduct constitutes unlawful deceptive and unconscionable trade practices. Defendants' conduct was consumer oriented and this conduct had broad impact on consumers at large. Defendants made materially misleading misrepresentations regarding the addictive nature of opioids they manufactured, marketed, and distributed.

353. Defendants made materially misleading misrepresentations about opioids they sold, and which were prescribed, in the United States, including Mississippi, during all pertinent times.

354. As fully described above, be advertising, manufacturing, marketing, distributing, and selling opioids which they had misrepresented to Plaintiffs who received prescriptions for Defendants' misrepresented opioids, Defendants engaged in unlawful, deceptive, and unconscionable trade practices.

355. Defendant's misleading misrepresentations regarding opioids they manufactured, marketed, and distributed were material, and they were likely to deceive reasonable consumers and health care providers.

356. Plaintiffs and health care providers were deceived by Defendants' material misrepresentations as described in this Complaint.

357. Plaintiffs who were prescribed and purchased Defendants' opioids in the United States, including Mississippi, were injured by Defendants' unlawful deceptive and unconscionable trade practices.

358. The injuries suffered by Plaintiffs were proximately caused by Defendants' deceptive conduct. But for the deceptive scheme perpetrated by Defendants, which included material misrepresentations made by Defendants, their Front Groups, and KOLs, Plaintiffs would not have paid for opioid prescriptions for chronic pain. In addition, but for Defendants' deceptive conduct, Plaintiffs would not have paid for treatment addressing addiction-involving opioids. Plaintiffs' injuries and damages were directly caused by Defendants' deceptive conduct.

359. As a result of Defendants' unlawful deceptive and unconscionable trade practices, Plaintiffs, pursuant to Miss. Code Ann. § 75-24-1, *et seq.* are entitled to damages and such other orders and judgments which may be necessary to disgorge Defendants' ill-gotten gains and to restore to Plaintiffs any money paid for Defendants' materially misrepresented opioids. Plaintiffs are also entitled to collect from Defendants damages they suffered by paying for treatment to address addiction involving opioids and/or opiates.

COUNT VI
MEDICAL MONITORING AND
OTHER INJUNCTIVE RELIEF
(Against all Defendants)

360. Plaintiffs repeat and reallege each of the above allegations as if fully set forth again.

361. Through the massive over prescription of opioids that has occurred as a result of Defendants' deceptive conduct, Plaintiffs are at increased risk for addiction and/or overdose.

362. Early detection of problematic drug use – through examination and testing – has significant value for Plaintiffs because such detection will help them monitor and minimize the harm therefrom.

363. Due to the receipt of opioid prescriptions by Plaintiffs, surveillance in the form of periodic medical examinations is reasonable and necessary, because such surveillance will provide early detection and diagnosis of the often cunning and baffling warning signs for drug addiction, which – once it takes hold – is so powerful that it destroys and ends lives. As a remedy for the deceptive and unconscionable conduct alleged in this Complaint, Defendants should be required to fund a medical monitoring program designed to identify and combat early signs of problematic drug use and addiction.

COUNT VII
UNJUST ENRICHMENT
(Against all Defendants)

364. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

365. Defendants acted willfully, wantonly, and with conscious disregard of the rights of the Plaintiffs and United States citizens, including Mississippi residents.

366. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by Plaintiffs and United States citizens, including Mississippi residents.

367. In exchange for the opioid purchases, and at the time Plaintiffs and residents of the United States, including Mississippi, made these payments, Plaintiffs and residents of the United States, including Mississippi, expected that Defendants had provided all of the necessary

and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

368. Defendants, through the wrongful conduct described above, have been unjustly enriched at the expense of Plaintiffs.

369. In equity and good conscience, it would be unjust and inequitable to permit defendants to enrich themselves at the expense of the Plaintiffs and residents of the United States, including Mississippi.

370. By reason of the foregoing, Defendants must disgorge its unjustly acquired profits and other monetary benefits from its unlawful conduct and provide restitution to the Plaintiffs.

371. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor and Manufacturer Defendants, attorney fees and costs, and pre- and post- judgment interest.

COUNT VIII
NEGLIGENCE
(Against all Defendants)

372. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

373. Distributor and Manufacturer Defendants have a duty to exercise reasonable care in the distribution of opioids.

374. Distributor and Manufacturer Defendants breached this duty by failing to take any action to prevent or reduce the distribution of the opioids.

375. As a proximate result, Distributor and Manufacturer Defendants and their agents have caused Plaintiffs to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids. Plaintiffs have borne the massive costs of these illnesses and conditions by having to provide necessary financial resources for care, treatment facilities, and law enforcement in relation to opioid use and abuse.

376. Distributor and Manufacturer Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

377. Distributor and Manufacturer Defendants' acts and omissions imposed an unreasonable risk of harm to other separately and/or combined with the negligent and/or criminal acts of third parties.

378. Distributor and Manufacturer Defendants are in a class of a limited number of parties that can legally distribute opioids, which places it in a position of great trust by the Plaintiffs.

379. The trust placed in Distributor and Manufacturer Defendants by the Plaintiffs through the license to distribute opioids creates a duty on behalf of Distributor and Manufacturer Defendants to prevent diversion of the medications it supplies to illegal purposes.

380. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to Plaintiffs from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

381. Distributor and Manufacturer Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

382. Distributor and Manufacturer Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution.

383. Distributor and Manufacturer Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

384. Distributor and Manufacturer Defendants are in exclusive control of the management of the opioids it manufactured and distributed to pharmacies and drug stores in the United States, including Mississippi.

385. Plaintiffs are without fault and the injuries to Plaintiffs would not have occurred in the ordinary course of events had Distributor and Manufacturer Defendants used due care commensurate to the dangers involved in the distribution and manufacture of opioids.

PUNITIVE DAMAGES

386. Plaintiffs reallege all paragraphs of this Complaint as if set forth fully herein.

387. By engaging in the above-described intentional and/or unlawful acts or practices, Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or grossly negligent manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiffs with fraud, oppression, and/or malice, and/or were grossly negligent in failing to perform the duties and obligations imposed upon them under the applicable Federal and State law.

388. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger to Plaintiffs by these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence, and the safety of the community, and an award of punitive damages is appropriate, as punishment and deterrence.

389. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and gross negligence, and exhibited an entire want of care that would raise the presumption of a conscious reckless indifference to consequences.

VII. JURY DEMAND

390. Plaintiffs hereby demand a trial by jury of their claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for judgment against Defendants as follows:

- A. For an order awarding, as appropriate, damages, restitution, or disgorgement to Plaintiffs including all monetary relief to which Plaintiffs are entitled;
- B. For declaratory, injunctive, and/or other equitable relief, which orders Defendants to establish programs to educate Mississippi on the risks associated with Opiate prescriptions;
- C. For a preliminary injunction, permanent injunction, or declaratory judgment to implement testing of Plaintiffs to detect early signs of problematic drug use and addiction;
- D. For an order awarding pre-judgment and post-judgment interest; and
- E. For an order awarding attorneys' fees and costs.

Respectfully submitted this the 25th day of March, 2020.

/s/John Arthur Eaves, Jr.
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